

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

K.M.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/085,820	05/28/98	WANG	H CIT98-01PA

HM22/0517

PATRICIA GRANAHAN
HAMILTON BROOK SMITH & REYNOLDS
TOW MILITIA DRIVE
LEXINGTON MA 02173-7499

EXAMINER

ANDRES, J

ART UNIT	PAPER NUMBER
1646	18

DATE MAILED: 05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No. 09/085,820	Applicant(s) WANG ET AL.
	Examiner Janet L Andres	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 March 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 and 15-75 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,13,15-40 and 44-66 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5,7-12,41-43 and 67-75 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 1 March 2001 in paper no. 8 is acknowledged. Claims 1-13 and 15-75 are pending in this application. Claims 4, 6, 13, 15-40, and 44-66 are withdrawn from consideration as being drawn to a non-elected invention.
2. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

3. The rejection of claims 3, 5, 10, and 42 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in response to Applicant's arguments. The Examiner agrees that one of skill could identify other member of the ephrin/eph families meeting the limitations of the claims without undue experimentation.
4. The rejection of claims 3, 5, 10, and 42 under 35 U.S.C. 112, first paragraph, as lacking written description is withdrawn in response to Applicant's arguments.

Claim Rejections Maintained/New Grounds of Rejection

5. The rejection of claims 1, 2, 8, 9, and 41 as lacking enablement commensurate with the scope of the claims is maintained.

Applicant argues that it is art-standard to classify new genes into gene families by structural and functional features exemplified in the prior art and that it would be routine to determine whether new member of the ephrin/eph families are artery or vein specific. The Examiner agrees with Applicant's arguments, as discussed above, and this basis of the rejection is withdrawn. However, as stated in the previous office action, since ephrins and ephs are widely distributed, the characteristics that define a molecule as an ephrin or an eph do not inherently

Art Unit: 1646

define it as an artery or vein-specific protein. Thus, without further teaching as to what characteristics of these molecules result in their being artery- or vein-specific, the identification of an ephrin/eph pair does not provide sufficient guidance to allow one of skill to identify other artery- or vein-specific molecules. While one of skill could readily screen arterial and venous tissue for other ephrin and eph molecules, the claims encompass molecules that need have no structural or functional relation whatsoever to the two molecules Applicant has described, including molecules that are not yet known in the art. The specification provides no basis for the skilled artisan to identify such molecules. Applicant quotes Dr. Folkman as stating that the instant invention provides the earliest known markers distinguishing arterial and venous endothelium. Applicant further states that the purpose of the Shutter reference was to indicate the predictability of identifying other artery-specific molecules, due to advances enabled by Applicant's invention, not to provide support for enablement at the time of the invention. The Examiner agrees that, based on Applicant's discovery, one of skill might be motivated to look for other artery- or vein-specific molecules. However, it is required under 35 U.S.C. 112, first paragraph, that the invention be enabled at the time of filing. MPEP §2164.01 states:

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Here, since there is no guidance as to how one of skill might identify molecules within the scope of the claim yet not identifiable as ephrins or ephs, it would require undue experimentation to practice the invention as broadly claimed.

Art Unit: 1646

6. The rejection of claims 1, 2, 8, 9, and 41 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained. The Examiner agrees that one skilled in the art could identify the genus of "artery-specific Ephrin family" and "vein-specific EPH family". However, as stated above, the claims encompass molecules unrelated to these families, and Applicant has provided no particular structures or characteristics to identify the geni as broadly claimed.

7. The rejection of claims 1-3, 5, and 7 under 35 U.S.C. 112, second paragraph, is maintained. As stated in the previous office action, the limitations of "interaction" are not described in the specification so that one of skill in the art would know what was intended.

8. The objection to claims 12 and 43 is maintained, since the Examiner has not found the base claims to be allowable. Claims 10 and 42 are similarly objected to as depending from a rejected base claim but are otherwise allowable.

9. Applicant is advised that should claims 67, 68, 69, and 71 be found allowable, claims 3, 7, 10, and 12 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

Art Unit: 1646

filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-3, 5, 7-10, 12, 41-44, 67-69, 71 and 72 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 5, 7-10, 12, 42-44, 3, 7, 10, 12, and 14 respectively of copending Application No. 09/687652. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 70 and 73-75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 71, 72, and 8 respectively of copending Application No. 09/687652. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope.

Copending claim 14 is drawn to a method of delivering an angiogenic drug by targeting ephrin

B2. Instant claim 70 is drawn to a method of delivering an angiogenic drug by targeting an ephrin family member. Since the example provided in the specification is ephrin B2 it clearly would have been *prima facie* obvious to target to this species. Instant claims 73 and 74 are

drawn to methods of altering blood vessel development. Copending claims 71 and 72 are drawn

Art Unit: 1646

to methods for altering angiogenesis in a tumor. Since angiogenesis is well known in the art to be essential for tumor growth and angiogenesis inhibitors to block tumor growth are the subject of extensive research, such an application of the instant invention would be *prima facie* obvious. Instant claim 75 is drawn to a method of delivering an angiogenic drug; copending claim 8 is drawn to a method of delivering a drug. Thus the copending claim encompasses the instant claim; delivery of angiogenic drugs is contemplated in the copending application on p. 16 and thus it would be *prima facie* obvious to deliver an angiogenic drug.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly

Art Unit: 1646

signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

May 9, 2001

Yvonne Eyer
YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600